

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-012/S-016

APPROVED LABELING

Drug Facts

Active ingredient (in each tablet)
Ibuprofen 200 mg

Purpose
Pain reliever

Use treats pain of migraine headache

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives • facial swelling • asthma (wheezing) • shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- never had migraines diagnosed by a health professional
 - a headache that is different from your usual migraines
 - the worst headache of your life
 - fever and stiff neck
 - headaches beginning after or caused by head injury, exertion, coughing or bending
 - experienced your first headache after the age of 50
 - daily headaches
 - a migraine headache so severe as to require bed rest
 - problems or serious side effects from taking pain relievers or fever reducers
 - stomach pain
 - vomiting with your migraine headache
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Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
 - taking any other drug
 - taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
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Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
 - migraine headache pain is not relieved or gets worse after first dose
 - stomach pain or upset gets worse or lasts
 - new or unexpected symptoms occur
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If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults:	<ul style="list-style-type: none">• take 1 or 2 tablets with a glass of water• the smallest effective dose should be used• if symptoms persist or worsen, ask your doctor• do not take more than 2 tablets in 24 hours for pain of migraine unless directed by a doctor
under 18 years of age:	<ul style="list-style-type: none">• ask a doctor

Other information

- do not use if neck wrap or foil inner seal imprinted "Safety Seal" is broken or missing
 - store at 20 – 25° C (68 – 77° F)
 - see end of panel for lot number and expiration date
- (For gelcaps only • avoid high humidity and excessive heat above 40° C (104° F) *will be added)

Inactive ingredients carnauba wax, cornstarch, hydroxypropyl methylcellulose, iron oxide black, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, titanium dioxide

Questions or comments? Call toll-free 1-800-962-5357
